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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,638	01/29/2004	Paul S. Charlson	VPI/02-128 US	5416
27916	7590	02/22/2007	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			CHANG, CELIA C	
		ART UNIT	PAPER NUMBER	
		1625		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/22/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/767,638	CHARIFSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 October 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 22-25, 30 and 31 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-21 and 26-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group II, compound I-105 of claim 20 in the reply filed on Oct. 9, 2006 is acknowledged. The traversal is on the ground(s) that groups I and III should be combined with group II. This is not found persuasive because it was evidence by the prior art that when W is N, the compounds exhibits decreased antimicrobial activity (see CA 93:39290), thus, would not be considered a prima facie obvious core variation for the claims. Based on the species election and applicants' argument, groups I and II are joined and the restriction between groups I or II, and III based on W being CH or CF, and W is N compound is maintained for reason of record and the newly available evidence.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 reading on compounds and composition wherein W is CH or CF are prosecuted together with claims 26-29 which are rejoined to the extend of W is CH or CF compounds. Claims 22-25, 30-31 and the remaining subject matter of claims 1-21 wherein W is N are withdrawn from consideration.

2. Claims 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-27 are ambiguous and confusing. It is not understood what does it mean, in claim 26, when the scope of the claim is drawn to "decreasing bacterial quantity". Please note, decreasing number of bacterial, if it does not affect the infective ability of the bacterial does not

result in a patentable utility. The scope is very confusing as to whether this claim treats infection or not.

It is self conflicting, in claim 27, when the method is “preventing” a bacterial infection in a “patient”. When a patient is infected, there could not be any de novo prevention. A maintenance dose in a patient to be infection free, is encompassed by the term treatment. Further, it is not understood what does it mean, in claim 27, when the scope of the claim is “lessening the severity” of a bacterial infection. Is this treatment or not treatment? When does it become treatment? It is recommended that the term preventing or lessening the severity be deleted as superfluous ambiguous terms.

3. Claims 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There is limited disclosure of the instantly claimed compound being tested positive in an *S. aureus* MIC assay. *S. aureus* is one gram positive bacteria. Testing position against one gram positive bacterial does not offer enabling support for the scope of the claims wherein “any and all” bacterial infection is encompassed. No enablement support from this one bacteria activity can be extrapolated to broad spectrum “antibacterial” activity. This is a scope of enablement rejection.

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4. Claims 1-21, 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 23-26 of copending Application No. 10/459,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are fully embraced by the copending claims because the instant claims are limited to the copending claims wherein R3 is T-Ar, wherein T is  $(CH_2)^y$  and y is 0 compounds i.e. a ring moiety which is directly linked to the bicyclic core. There is no good reason why a fully embraced more limited scope should be extended in their exclusive rights continuously.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. No claims allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Feb. 5, 2007

  
Celia Chang  
Primary Examiner  
Art Unit 1625